and *pentobarbital sodium capsules* were being held for sale at the Fayetteville Pharmacy after shipment in interstate commerce, the defendant caused 1 bottle of the *Combisul-DM tablets* and 1 bottle of the *dextro-amphetamine sulfate tablets* to be dispensed without the prescription of a physician to purchasers in the original bottles in which the tablets had been shipped in interstate commerce; and, in addition, the defendant caused various quantities of the *pentobarbital sodium capsules* and the *Combisul-DM tablets* to be repacked and dispensed without prescriptions, which acts of the defendant resulted in the dispensed drugs being misbranded.

NATURE OF CHARGE: *Combisul-DM tablets* and *dextro-amphetamine sulfate tablets* (dispensed in original bottles). Misbranding, Section 502 (f) (1), the labeling of the drugs failed to bear adequate directions for use. (The bottles in which the tablets were shipped in interstate commerce bore no directions for use since they were exempted from such requirement by the statement on the label "Caution: To be dispensed only by or on the prescription of a physician." The act of the defendant in dispensing such drugs without a physician's prescription caused the exemption to expire.)

Pentobarbital sodium capsules and *Combisul-DM tablets* (repackaged portions). Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged capsules failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the repackaged *Combisul-DM tablets* were not designated solely by a name recognized in an official compendium and were fabricated from two or more ingredients, and their label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the repackaged *pentobarbital sodium capsules* and *Combisul-DM tablets* failed to bear adequate directions for use; and, Section 502 (f) (2), the repackaged *Combisul-DM tablets* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: May 15, 1952. A plea of guilty having been entered, the court imposed a fine of $104.

3866. Misbranding of Nembutal capsules and Benzedrine Sulfate tablets. U. S. v. Lew Wallace (Wallace Rexall Drugs), John W. Gordon, Jr., and George M. Smith. Pleas of nolo contendere. Fine of $50 against each defendant. (F. D. C. No. 28136. Sample Nos. 53420-K, 53885-K, 53890-K, 53898-K, 53900-K, 53913-K, 53968-K, 53969-K, 54126-K.)

INFORMATION FILED: September 14, 1950, Southern District of Mississippi, against Lew Wallace, a partner in the firm of Wallace Rexall Drugs, Laurel, Miss., and against John W. Gordon, Jr., and George M. Smith, pharmacists in the business.

ALLEGED VIOLATION: Between the approximate dates of June 1 and August 4, 1949, while a number of *Nembutal capsules* and *Benzedrine Sulfate tablets* were being held for sale at Wallace Rexall Drugs after shipment in interstate commerce, various quantities of the drugs were repacked and sold without a prescription, which acts resulted in the repackaged drugs being misbranded.

Lew Wallace was charged with making 1 sale of *Benzedrine Sulfate tablets;* George M. Smith was charged with 2 sales of *Nembutal capsules* and 1 sale of *Benzedrine Sulfate tablets;* and John W. Gordon, Jr., was charged with 4 sales of *Nembutal capsules* and 1 sale of *Benzedrine Sulfate tablets.*

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing accurate statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), the repackaged *Benzedrine Sulfate tablets* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the repackaged *Nembutal capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: On October 17, 1951, upon the basis of pleas of nolo contendere entered by John W. Gordon, Jr., and George M. Smith, the court imposed a fine of $50 against each defendant.

On October 31, 1952, following a plea of nolo contendere by Lew Wallace, the court imposed a fine of $50 against this defendant.

3867. Adulteration and misbranding of dextro-amphetamine sulfate tablets. U. S. v. 11 Bottles * * *. (F. D. C. No. 31382. Sample No. 11174-L.)

LIBEL FILED: July 23, 1951, Northern District of Ohio.

ALLEGED SHIPMENT: On or about March 1 and 15, 1951, by the International Pharmaceutical Laboratories, from Great Neck, N. Y.

PRODUCT: 11 unlabeled bottles of *dextro-amphetamine sulfate tablets* at Cleveland, Ohio.

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), a substance, namely 4.2-milligram amphetamine tablets, had been substituted for 5-milligram *dextro-amphetamine sulfate tablets.*

Misbranding, Section 502 (i) (2), the article was an imitation of another drug; Section 502 (i) (3), it was offered for sale under the name of another drug; Sections 502 (b) (1) and (2), it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (1), its label failed to bear the common or usual name of the drug, amphetamine sulfate tablets; Section 502 (f) (1), its labeling failed to bear adequate directions for use; and, Section 502 (f) (2), its labeling failed to bear such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, and against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users.